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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,976	04/02/2007	Flemming Kjaergaard Christensen	PATRADE	7548
James C. Wray 1493 Chain Bridge Road Suite 300 McLean, VA 22101			EXAMINER MI, QIUWEN	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 12/07/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/577,976

Applicant(s)

CHRISTENSEN, FLEMMING  
KJAERGAARD

Examiner

QIUWEN MI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 4-20 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 8-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 7 and 11-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **CONTINUED EXAMINATIONS**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/11/09 has been entered.

Applicant's amendment in the reply filed on 9/11/09 is acknowledged, with the cancellation of claims 2 and 3, and the additional newly added Claims 13-20. Claims 1, and 4-20 are pending. Claims 6, and 8-10 are withdrawn from further consideration as being drawn to nonelected inventions and species. **Claims 1, 4, 5, 7, and 11-20 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

### **Claim Rejections –35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 7, and 11-20 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Yamashita (JP 06128121 A), in view of Aizawa et al (JP 58079912 A).

Yamashita teaches cosmetic preparations that contain *Aspalathus linearis* extract as active ingredient and have the effect of providing moisture to the skin and hair and preventing skin aging [0001]. Yamashita also teaches as a result of further research, the inventor found that the application of a cosmetic preparation containing an *Aspalathus linearis* extract to the skin has effects against skin aging, such as wrinkling, pigmentation, and so forth, caused by ultraviolet radiation, and its application to the hair (thus a topical administration to the scalp) does not make the hair sticky and, moreover, has the effect of enhancing the hair-moisturizing effect [0004]. Yamashita further teaches the cosmetic preparation of the present invention is prepared by blending the aforesaid active ingredient in a known formulation that is acceptable for the skin or hair application, and its blending quantity is usually from 0.001 to 30.0% by weight, preferably from 0.01 to 20% by weight (thus overlaps with the claimed range of 1-20%, 1%. 2-12%, 3-10%, 5-8%, 1-3%), of the cosmetic preparation as a whole. Yamashita teaches as noted earlier, the known formulation of the cosmetic composition means any formulation that can be applied externally, and some examples thereof includes, as skin-use preparations, cataplasm, plaster, paste (thus a medicament), cream, ointment (thus a medicament), aerosol, emulsion, lotion, milky lotion, essence, pack, gel, powder, foundation, suncare, bath salt, soap, and so forth and, as hair-use preparation, shampoo (thus a topical administration to the scalp), rinse, hair tonic, hair liquid, hair spray, hair form, and so forth [0010]. Yamashita also teaches a composition containing an ancillary agent purified water (page 11, [0028]).

Yamashita does not teach the incorporation of the extract of deep-sea fish.

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Aizawa et al teach a cosmetic is characterized by the fact hat it is prepared by compounding an oil derived from a deep-sea fish (thus an extract of a deep sea fish) (claim 1). Aizawa et al teach the inventors found that an oil obtained from a deep-sea fish, which is a new compound in the cosmetics industry, has excellent physical properties which the existing fish oil does not have, and that cosmetics which are prepared by compounding this are highly safe, have an unprecedented usability and excellent feel in touch, and achieved this invention based on this knowledge (page 2, last paragraph). In the examples, Aizawa et al teach the deep-sea fish oil used in this invention, by using it as an oily ingredient in the constituents of the existing cosmetic products, improves the quality of the cosmetics and provides a cosmetic which has less oiliness and gives a refreshing, moist, and smooth feeling to the skin when used (page 3, last paragraph bridging page 4). In the examples, deep sea fish oil was used 1% in cream shampoo (thus a topical administration to the scalp) (thus within the claimed range of 0.25-2%) (page 11, exemplary embodiment 6), 3% (page 12, exemplary embodiment 7), 5% (pages 8-9, exemplary embodiment 3), 6% (page 4, exemplary embodiment 1), 10% (page 6, exemplary embodiment 4; page 10, exemplary embodiment 5) (thus about 12.40%; thus within the claimed range of 10-15%). Aizawa et al also teach a composition containing an ancillary agent purified water (pages 4-5, exemplary embodiment 1).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the deep sea fish oil (thus an extract) from Aizawa et al since Aizawa et al teach it is having high safety, excellent feeling and physical properties and low oiliness, and giving refreshing, moist and smooth feeling to the skin.

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Since both of the compositions yielded beneficial results in cosmetic industry, one of ordinary skill in the art would have been motivated to make the modifications to combine the teachings of the references together.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 1, 4, 7, and 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamashita and Aizawa et al as applied to claims 1, 7, and 11-20 above, and further in view of Shibata et al (JP 08310939 A).

The teachings of Yamashita and Aizawa et al are set forth above and applied as before.

The combination of Yamashita and Aizawa et al do not specifically teach the incorporation of horsetail extract into the composition.

Shibata et al teach external fair-skin preparation contains extract of Equisetaceae family, Equisetum genus particularly Equisetum arvense L., Equisetum hyemale L. or Equisetum debile Roxb., at concentration of 0.05-20.0 wt.%, excluding Equisetum giganteum. Raw materials are extracted with conventional solvent (e.g. MeOH, EtOH, aqueous alcohols, acetone and EtOAc) and resultant extract is added to conventional external preparation bases including cosmetics together with known additives and carriers. It is used to prevent and treat pigmentation, spots, freckles and chloasma at concentration of 0.005-20.0 (preferably 0.01-10.0) wt.% in external composition. Composition is non-toxic. In an example, extracts of Equisetum arvense L.,

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*Equisetum myemale* L. and *Equisetum debile* Roxb inhibited melanin formation at concentration of 0.01 wt.% in cultured B16 melanoma cells. At same concentration, these extracts inhibited tyrosinase activity at rate of 98, 97 and 98%, respectively (see Abstract, the rejection is based on the Abstract, full translation of the document is attached).

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use extracts of *Equisetum arvense* from Shibata et al since Shibata et al teach it is used to prevent and treat pigmentation, spots, freckles and chloasma. Therefore, it would also have been obvious one of ordinary skill in the art to incorporate the extracts of *Equisetum arvense* from Shibata into the composition of Yamashita to enhance the antiaging effect such as pigmentation.

Since all of the compositions yielded beneficial results in cosmetic industry, one of ordinary skill in the art would have been motivated to make the modifications to combine the teachings of the references together.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 1, 5, 7, and 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamashita and Aizawa et al as applied to claims 1, 7, and 11-20 above, and further in view of Larsen et al (US 2005/0113293).

The teachings of Yamashita and Aizawa et al are set forth above and applied as before.

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The combination of Yamashita and Aizawa et al do not specifically teach the incorporation of diacetyl boldine into the composition.

Larsen et al teach the use of a lipid extract of *Skeletonema costatum* which contains the alkaloid boldine in a cosmetic composition for the amelioration of the signs of skin ageing. Said lipid extract and the compound boldine improves the gap junctional intercellular communication in keratinocytes, fibroblasts and pre-adipocytes. The inventors show that treatment with boldine increases the content of connexin 43 in keratinocytes of middle aged and elderly people to the content found in keratinocytes of young people in a dose dependent manner with a boldine concentration of 50 nM being optimal. Since an increase of the cellular content of connexin 43 must contribute to a facilitation of gap junctional intercellular communication the compound boldine can be useful in the present invention [0743].

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use boldine from Larsen et al since Larsen et al teach it ameliorates the signs of skin ageing. Therefore, it would also have been obvious one of ordinary skill in the art to incorporate boldine from Larsen et al into the composition of Yamashita to enhance the antiaging effect.

Since all of the compositions yielded beneficial results in cosmetic industry, one of ordinary skill in the art would have been motivated to make the modifications to combine the teachings of the references together. Regarding the limitation to the use of boldine derivative, diacetyl boldine, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.



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From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that “The Examiner’s rejections are all based on precisely an “obvious to try” holding which has been repeatedly reversed by the Courts. A statement that modifications of the prior art to meet the claimed invention would have been “well within the ordinary skill of the art at the time the claimed invention was made” because the references relied upon teach that all aspects of the claimed invention were individually known in the art (emphasis supplied) is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). \*\*\*>JR]jections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” KSR, 550 U.S. at \_\_\_, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)’ (page 5, last paragraph bridging page 6). Applicant also argues that “Moreover, nothing in any of the references teach or suggest a combination as effected by the Examiner. The mere fact that references can be combined or modified does not render the resultant combination obvious unless \*\*>the results would have been predictable to one of ordinary skill *in the art*. *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1396 (2007)” (page 6, last paragraph).

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Applicant argues that there is no specific suggestion or teaching in the references to combine prior art. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of invention. In addition, KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, -- USPQ2d--, slip op. at 20 (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (available at <http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>).

### **Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Examiner, Art Unit 1655